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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,007	08/17/2001	Daniel Scherman	03806-0512	2754

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EXAMINER	
SHUKLA, RAM R	
ART UNIT	**PAPER NUMBER**
1632	11

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 09/931,007	Applicant(s) SCHERMAN ET AL.	
	Examin r Ram R. Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 December 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Examiner Shukla, whereas any inquiries relating to formal matters should be directed to Ms. Phillips, Patent Analyst. The phone numbers for Examiner Shukla and Patent Analyst Phillips are provided at the end of this office action.

2. Response filed 12-30-02 has been received.

3. The restriction requirement set forth in the previous office action of 10-1-02 is hereby revoked and the following new restriction requirement is issued.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9-18, 20-28, 30-39 and 41-45, 83-100, drawn to a method of regulating the expression of a transgene of interest in vivo in an animal comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, wherein the nucleic acids are carried in a plasmid or viral vector, classified in 424, subclass 93.1.

II. Claims 1 and 8, drawn to a method of regulating the expression of a transgene of interest in vivo in an animal comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene which further comprises a sequence that can be recognized by a ribozyme, wherein the nucleic acids are carried in a plasmid or viral vector, classified in 424, subclass 93.1.

III. Claims 1, 24, 29, drawn to a method of regulating the expression of a transgene of interest in vivo in a mammal comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, wherein the nucleic acids are carried in a bacterium or parasite, classified in 424, subclass 93.4.

IV. Claims 1 and 40, drawn to a method of regulating the expression of a transgene of interest in vivo a plant comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, wherein the nucleic acids are carried in a plasmid or viral vector, classified in 435, subclass 468.

V. Claims 46-55, 57-70, 72-82, drawn to composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, wherein the nucleic acids are carried in a plasmid or viral vector, classified in 435, subclass 320.1.

VI. Claims 46 and 56, drawn to a composition comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα,

and a second nucleic acid comprising a sequence of an inhibitory transgene which further comprises a sequence that can be recognized by a ribozyme, wherein the nucleic acids are carried in a plasmid or viral vector, classified in 435, subclass 320.1.

VII. Claims 46, 66, and 71, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, wherein the nucleic acids are carried in a bacterium or parasite, classified in 435, subclass 252.3.

VIII. Claims 101-106 drawn to a transgenic animal, which carries a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript and a second nucleic acid comprising a sequence of an inhibitory transgene, each of the sequences are under the control of separated transcriptional promoters, and both activities are regulated by at least one external agent, classified in 800, subclass 8.

IX. Claims 107-112, drawn to a transgenic plant, which carries a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript and a second nucleic acid comprising a sequence of an inhibitory transgene, each of the sequences are under the control of separated transcriptional promoters, and both activities are regulated by at least one external agent, classified in 800, subclass 295.

5. In addition, upon the election of any of groups I-XII, further election of the following patentably distinct species of the claimed invention is required:

I) Inhibitory transcript: an antisense RNA, an RNA capable of forming a triple helix with a portion of the nucleic acid, or a ribozyme.

II) Method of introducing the nucleic acids into target tissue or cell: a physical/mechanical method, or a chemical/biochemical agent.

The inhibitory transcripts are distinct because they are structurally and functionally distinct.

The method of introducing the nucleic acids into target tissue or cell and the administration methods are distinct because they differ at least in method steps, reagents, dosages, schedules used, response variables and criteria for success.

6. It is noted that claims 84-100 are drawn to methods of using the compositions are treatments. While the invention of group I is regarded as a method of in vivo gene expression and treatment and these claims have been grouped in this group, applicants are required to elect one disease for prosecution. It is emphasized that this is not species election, rather a restriction, since all the diseases are distinct and they will require distinct nucleic acids for treatment and the method steps will be different.

7. The inventions are distinct, each from the other because:
The inventions of the groups I and II are patentably distinct each from the other because they use nucleic acids that have different structure and function. For example, the nucleic acid used in the method of group II comprises a target sequence for a ribozyme, whereas the nucleic acid used in the method of group I does not.

The method of group III is distinct from the methods of groups I and II because the carrier of the nucleic acid is a bacterium or parasite. The route of administration and steps of the method of group III cannot be used for practicing the method of groups I and II.

The method of group IV is distinct from that of the method of groups I -III because it is carried out in a plant compared to an animal in the methods of groups

I-III. The steps of a method for gene administration and treatment in a plant cannot be used in an animal due to the differences in structure of animals and plants.

The inventions of the groups V-VII are patentably distinct each from the other because they are drawn to compositions that have different structure, function and utilities. For example, the nucleic acids of the groups V and VI are different because they have different sequence elements, whereas the bacterium of group VII is distinct from the nucleic acids of groups V and VI since it is a cell.

The transgenic animals of the group VIII are patentably distinct from the composition of group IX because the composition of groups IX is drawn to a transgenic plant. The structure, function and utilities of animals and plants are different.

8. Inventions of the groups V-IX and I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of the groups V-VII are used for making the transgenic animals or plants of groups VIII and IX or for practicing the methods of the groups I-IV.

9. As noted in the previous office action, misnumbered claims 77-113 have been renumbered as 76-112 under Rule 1.126.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

RAM R. SHUKLA, PH.D
PATENT EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632